EXHIBIT # 11

K012736

OCT 25 2001

510(k) Summary

In accordance with section 513(I) of the SMDA and as defined in 21 CFR Part 807.3 final rule dated December 14, 1994, this summary is submitted by:

The Kendall Company
15 Hampshire Street
Mansfield, MA 02048
Date Prepared: August 10, 2001

1. Contact Person

David A. Olson
Director, Regulatory Affairs
(508) 261-8530

2. Name of Medical Device

Classification Name: Needle, Hypodermic, Single Lumen

Common or Usual Name: Hypodermic Needle with Sharps Injury Prevention Feature.

3. Identification of Legally Marketed Device

The proposed Kendall Monoject® Safety Needle is substantially equivalent in intended use, design and function to Becton Dickinson's SafetyGlide™ Needle, 510(k) No. K951254 and the Concord/Portex (Sims) Needle-Pro®, 510(k) No. K911037.

4. Device Description

The proposed device consists of a sterile, single-lumen hypodermic needle with an attached safety shield. The segmented safety shield is designed to be extended over the needle and locked. Activation is performed by a finger-tip operation or by pressing the shield against a hard surface. Once activated, the safety shield is securely and permanently locked.

5. Device Intended Use

The proposed device is primarily intended to inject fluid into, or withdraw fluid from the body. The safety shield is designed to protect against sharps injuries when activated.

6. Product Comparison

The proposed device has the same technological characteristics as the predicate devices. Each device consists of a hypodermic needle with a manually operated safety feature.

7. Nonclinical Testing

Biocompatibility testing of the proposed device has demonstrated that it meets the requirements of guidelines presented in the 10993 ISO Standard, Part 1, with the FDA modified matrix presented in memorandum G95-1.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 25 2001

Mr. David A. Olson
Director, Regulatory Affairs
Tyco Healthcare
15 Hampshire Street
Mansfield, Massachusetts 02048

Re: K012736
Trade/Device Name: Monoject Safety Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Needle, Hypodermic, Single Lumen
Regulatory Class: Class II
Product Code: FMI
Dated: August 15, 2001
Received: August 16, 2001

Dear Mr. Olson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration

and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K012736

Device Name: Kendall Monoject Safety Needle

Indications For Use:

The primary function of the device is to inject fluids into, or withdraw fluids from, parts of the body below the surface of the skin. The needle stick prevention feature of the device helps prevent accidental needle sticks by shielding the needle after use.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Patricia Cusenza

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K012736

Prescription Use ✓ OR Over-The-Counter Use ___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)